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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SHIONOGI & CO., LTD., a Japanese company,

Plaintiff,

v.

INTERMUNE, INC., a Delaware corporation,

Defendant.

Case No. 3:12-CV-03495-EDL

ANSWER OF INTERMUNE, INC. TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR BREACH OF CONTRACT AND DECLARATORY RELIEF

Magistrate Judge Elizabeth D. Laporte
Courtroom E – 15th Floor
Trial Date: None Set

JURY TRIAL DEMANDED

Defendant InterMune, Inc. ("InterMune"), by and through its undersigned attorneys, answers the First Amended Complaint for Breach of Contract and Declaratory Relief ("First Amended Complaint") filed on behalf of Plaintiff Shionogi & Co., Ltd. ("Shionogi") as follows:

I. THE PARTIES

1. InterMune lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1.

2. InterMune admits the allegations in paragraph 2.

II. JURISDICTION

3. Paragraph 3 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 3, except admits that (i) InterMune is incorporated in Delaware and has its principal place of business in California, and (ii) Shionogi purports that this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332.

III. VENUE

4. Paragraph 4 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 4, except admits that (i) InterMune's principal place of business is Brisbane, California, which is located in San Mateo County, (ii) Brisbane, California is located within the Northern District of California, and (iii) Shionogi purports that, pursuant to 28 U.S.C. § 1391(a), venue is proper in this judicial district. InterMune also refers the Court to the Agreement for Collaboration to Exchange Documents from Clinical Studies between Shionogi and InterMune, effective as of May 27, 2004, as amended (the "Collaboration Agreement"), for its true and complete contents.

IV. INTRADISTRICT ASSIGNMENT

5. Paragraph 5 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 5, except admits that Shionogi purports that this action should be assigned to the San Francisco Division or the Oakland Division pursuant to N.D. Cal. Local Rule 3-2(d).

V. ALLEGATIONS

A. The Collaboration Agreement And Amendment

6. InterMune admits the allegations in the first sentence of paragraph 6. InterMune lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 6, except admits that InterMune licensed from Marnac, Inc. and KDL GmbH their worldwide rights, excluding Japan, Korea and Taiwan, to develop and commercialize pirfenidone for the treatment of all fibrotic diseases, including renal, liver and pulmonary fibrosis.

7. InterMune admits the allegations in the first sentence of paragraph 7. InterMune denies the allegations in the second sentence of paragraph 7 and refers the Court to the Collaboration Agreement for its true and complete contents.

8. InterMune denies the allegations in paragraph 8 and refers the Court to the Collaboration Agreement for its true and complete contents.

9. InterMune admits the allegations in the first sentence of paragraph 9. InterMune denies the allegations in the second sentence of paragraph 9 and refers the Court to the Collaboration Agreement for its true and complete contents.

10. InterMune denies the allegations in paragraph 10 and refers the Court to the Collaboration Agreement for its true and complete contents.

11. InterMune denies the allegations in paragraph 11 and refers the Court to the Collaboration Agreement for its true and complete contents.

B. Shionogi's IPF Clinical Trials

12. InterMune lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of paragraph 12. InterMune denies the allegations in the second sentence of paragraph 12, except admits that Shionogi's clinical trials of pirfenidone included a study referred to as SP2 and a study referred to as SP3.

13. InterMune denies the allegations in paragraph 13, except admits that SP2 was a Phase II clinical trial of pirfenidone.

14. InterMune denies the allegations in paragraph 14, except admits that SP3 was a Phase III clinical trial of pirfenidone.

15. InterMune denies the allegations in paragraph 15, except admits that Shionogi sought marketing authorization for pirfenidone from the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") and that in 2008 the PMDA granted Shionogi authorization to market pirfenidone in Japan for the purposes specified by the PMDA.

C. InterMune's IPF Clinical Trials

16. InterMune denies the allegations in paragraph 16, except admits that InterMune conducted clinical trials of pirfenidone referred to as PIPF-004 and PIPF-006.

17. InterMune admits the allegations in paragraph 17.

18. InterMune admits the allegations in the first sentence of paragraph 18. InterMune denies the allegations in the second and third sentences of paragraph 18.

D. InterMune Obtains An Exclusive License And Uses Shionogi's IPF Clinical Trial Documents As Pivotal Study Data In Its EU Marketing Authorization Application

19. InterMune denies the allegations in the first sentence of paragraph 19, except admits that in February 2010, it filed a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA") seeking approval to market pirfenidone in the European Union ("EU") for certain purposes specified therein. InterMune denies the allegations in the second sentence of paragraph 19.

20. InterMune denies the allegations in paragraph 20, except admits that, on May 13, 2010, InterMune exercised its Option to acquire an IPF Exclusive License (as those terms are defined in the Collaboration Agreement) for the EU.

21. InterMune denies the allegations in the first sentence of paragraph 21. InterMune lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 21.

22. InterMune denies the allegations in paragraph 22.

23. InterMune denies the allegations in paragraph 23, except admits that in December 2010, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA adopted a positive opinion recommending the granting of InterMune's MAA for pirfenidone within the EU for the purposes specified therein.

24. InterMune denies the allegations in paragraph 24, except admits that, effective February 28, 2011, the European Commission authorized the marketing of pirfenidone by InterMune under the trade name Esbriet® in all 27 member states of the EU for the purposes specified by the European Commission.

25. InterMune denies the allegations in paragraph 25.

26. InterMune denies the allegations in the first and second sentences of paragraph 26 and refers the Court to the following documents for their true and complete contents: (i) InterMune, Inc. Form 10-K for the fiscal year ended December 31, 2011; and (ii) InterMune, Inc. Form 10-Q for the quarterly period ended March 31, 2012. InterMune lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences of paragraph 26.

27. InterMune denies the allegations in paragraph 27, except admits that (i) Shionogi has informed InterMune that Shionogi believes it is entitled to royalties on InterMune's sales of Esbriet® in the EU, and (ii) InterMune has informed Shionogi that no such royalties are owed under the Collaboration Agreement.

28. InterMune denies the allegations in the first sentence of paragraph 28, except admits that it informed Shionogi that InterMune did not use any Shionogi "IPF clinical trial documents" as Pivotal Study Data in its EU MAA and that no royalties are due or owing under the Collaboration Agreement. The allegations in the second sentence of paragraph 28 state legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in the second sentence of paragraph 28.

FIRST CLAIM FOR RELIEF
(Breach of The Amended Collaboration Agreement And EU Exclusive License)

29. InterMune repeats and realleges each and every response contained above with the same force and effect as though fully set forth herein.

30. Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 30.

31. Paragraph 31 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 31.

32. Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 32.

33. Paragraph 33 states legal conclusions to which no response is required.

To the extent a response is required, InterMune denies the allegations in paragraph 33.

34. Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 34.

35. Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 35.

SECOND CLAIM FOR RELIEF
(Declaratory Relief Regarding The Parties' Respective Rights And Duties Under The Amended Collaboration Agreement And EU Exclusive License)

36. InterMune repeats and realleges each and every response contained above with the same force and effect as though fully set forth herein.

37. Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 37, except admits that (i) InterMune exercised its Option to acquire an IPF Exclusive License (as those terms are defined in the Collaboration Agreement) for the EU, (ii) the European Commission granted InterMune marketing approval for pirfenidone in the EU under the trade name Esbriet® for the purposes specified by the European Commission, and (iii) InterMune disagrees with Shionogi as to whether any royalties are due to Shionogi under the Collaboration Agreement with respect to sales of Esbriet® in the EU.

38. Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 38, except admits that Shionogi purports that InterMune disagrees with the allegations in paragraph 38.

39. Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 39, except admits that Shionogi purports that InterMune disagrees with the allegations in paragraph 39.

40. Paragraph 40 states legal conclusions to which no response is required. To the extent a response is required, InterMune denies the allegations in paragraph 40, except admits that Shionogi seeks certain declaratory relief.

VI. PRAYER FOR RELIEF

The Prayer for Relief contains statements of law or fact to which no responsive

pleading is required. To the extent a response is required, InterMune denies that Shionogi is entitled to any remedy or relief on its claims, either as requested or otherwise.

VII. DEMAND FOR JURY TRIAL

The Demand for Jury Trial states no allegations to which a response is required. To the extent a response is required, InterMune denies the allegations in the Demand for Jury Trial, except admits that Shionogi purports to demand a jury trial for all issues and causes of action for which it is entitled to a jury trial.

InterMune also denies each and every allegation in the Complaint not otherwise responded to above, including but not limited to, allegations appearing in headings.

AFFIRMATIVE DEFENSES

InterMune alleges the following as separate and distinct defenses to each and every cause of action asserted in the First Amended Complaint to which such defense is or may be applicable. By asserting these defenses, InterMune does not assume any burden of proof, persuasion or production not otherwise legally assigned to it.

First Affirmative Defense

The First Amended Complaint, and each and every claim alleged therein, fails to state a claim upon which relief can be granted.

Second Affirmative Defense

Shionogi's claims are barred, in whole or in part, by the doctrine of waiver.

Third Affirmative Defense

Shionogi's claims are barred, in whole or in part, by the doctrine of estoppel.

Fourth Affirmative Defense

Shionogi's claims are barred, in whole or in part, by the doctrine of unclean hands.

Fifth Affirmative Defense

Shionogi's claims are barred, in whole or in part, because Shionogi failed to mitigate any damages it may have suffered.

Sixth Affirmative Defense

Shionogi's claims are barred by a failure of a condition precedent to any royalty obligation owed by InterMune under the Collaboration Agreement.

Seventh Affirmative Defense

InterMune had a license to use Shionogi's clinical data in the manner that InterMune did without any obligation to pay Shionogi royalties.

Eighth Affirmative Defense

InterMune reserves the right to raise any additional affirmative or other defenses not asserted herein that it becomes aware of through discovery or other investigation.

WHEREFORE, InterMune respectfully requests that the Court:

1. Enter judgment against Shionogi and in favor of InterMune on all counts;

2. Dismiss Shionogi's First Amended Complaint with prejudice;

3. Award InterMune its costs and fees incurred in this action, including reasonable attorneys' fees, expert witness fees and out-of-pocket costs pursuant to Section 6.4 of the Collaboration Agreement; and

4. Grant such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

In accordance with Rule 38 of the Federal Rules of Civil Procedure and Civil L.R. 3-6(a), Defendant InterMune, Inc. respectfully demands a jury trial of all issues triable to a jury in this action.

Dated: September 17, 2012

LATHAM & WATKINS LLP
Patrick E. Gibbs

CRAVATH, SWAINE & MOORE LLP
Gary A. Bornstein

By: /s/ Patrick E. Gibbs
Patrick E. Gibbs

Attorneys for Defendant InterMune, Inc.